

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Carl D. Wahlstrand, Confirmation No. 6690  
Ruchika Singhal and  
Robert M. Skime

Serial No.: 10/731,869

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Examiner: Alyssa M. Alter

Group Art Unit: 3762

Docket No.: 1023-318US01

Title: MODULAR IMPLANTABLE MEDICAL DEVICE

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via the United States Patent and Trademark Office electronic filing system on September 11, 2009.

By:   
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REPLY BRIEF

Mail Stop Appeal Brief - Patents  
Commissioner for Patents  
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Sir:

This Reply Brief is responsive to the Examiner's Answer dated July 20, 2009. The period of response for filing this Reply Brief runs through September 20, 2009.

No fees are believed to be due at this time. Please charge any additional fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

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### STATUS OF CLAIMS

Claims 1–31 and 33–61 are pending and are the subject of this appeal. Claims 1–31 and 33–61 are set forth in Appendix A of the Appeal Brief filed on February 19, 2009. Originally filed claim 32 was canceled in an Amendment filed on November 28, 2005. Claims 58–61 were added in an Amendment filed on June 8, 2007.

Claims 1–4, 6–9, 11–25, 27–30, 33–44, 46–49, 51–54, 56, and 58–61 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Berrang et al. (U.S. Patent No. 6,358,281, hereinafter “Berrang”). Claim 55 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Berrang, or, in the alternative, rejected under 35 U.S.C. § 103(a) as being obvious over Berrang. Claims 5, 10, 26, 31, 45, 50, and 57 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Berrang.

Claims 1–31 and 33–61 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–23 of copending Application No. 10/731,638 (now U.S. Patent No. 7,212,864), claims 1–14 of copending Application No. 10/730,878 (U.S. Publication No. 2004/0176816), claims 1–23 of copending Application No. 10/731,699 (U.S. Publication No. 2004/0172090), claims 1–54 of copending Application No. 10/730,873 (now U.S. Patent No. 7,242,982), claims 1–27 of copending Application No. 10/731,867 (U.S. Publication No. 2004/0176673), and claims 1, 2, and 14–16 of copending Application No. 10/731,868 (U.S. Publication No. 2004/0173221).

## **GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

Appellant submits the following grounds of rejection to be reviewed on appeal:

- (1) The first ground of rejection to be reviewed on appeal is the rejection of claims 1–4, 6–9, 11–25, 27–30, 33–44, 46–49, 51–54, 56, and 58–61 under 35 U.S.C. § 102(e) as being anticipated by Berrang.
- (2) The second ground of rejection to be reviewed on appeal is the rejection of claim 55 under 35 U.S.C. § 102(e) as being anticipated by Berrang, or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Berrang.
- (3) The third ground of rejection to be reviewed on appeal is the rejection of claims 5, 10, 26, 31, 45, 50, and 57 under 35 U.S.C. § 103(a) as being unpatentable over Berrang.
- (4) The fourth ground of rejection to be reviewed on appeal is the provisional rejection of claims 1–31 and 33–61 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–23 of copending Application No. 10/731,638 (now U.S. Patent No. 7,212,864), claims 1–14 of copending Application No. 10/730,878 (U.S. Publication No. 2004/0176816), claims 1–23 of copending Application No. 10/731,699 (U.S. Publication No. 2004/0172090), claims 1–54 of copending Application No. 10/730,873 (now U.S. Patent No. 7,242,982), claims 1–27 of copending Application No. 10/731,867 (U.S. Publication No. 2004/0176673), and claims 1, 2, and 14–16 of copending Application No. 10/731,868 (U.S. Publication No. 2004/0173221).

## ARGUMENT

In the Examiner's Answer to Appellant's Appeal Brief, the Examiner provided a clarification of the rejection of the claims and a new ground of rejection. For brevity, this Reply Brief only addresses aspects of these new arguments. Accordingly, this Reply Brief is not intended to address all arguments provided in the Examiner's Answer, and Appellant requests full consideration of all arguments set forth in the Appeal Brief filed on April 17, 2009. Appellant respectfully requests separate review of each set of claims argued under separate headings in the Appeal Brief.

## NEW GROUND OF REJECTION PRESENTED IN THE EXAMINER'S ANSWER

The Examiner presented a new ground of rejection in the Examiner's Answer. In particular, the Examiner withdrew the rejection of claim 45 under 35 U.S.C. § 102(e) as being anticipated by Berrang, and rejected claim 45 as being obvious under 35 U.S.C. § 103(a) in view of Berrang.<sup>1</sup> The Examiner's new ground of rejection of claim 45 is erroneous and should be reversed.

Claim 45 specifies that the implantable medical device of independent claim 42 includes a recharge coil located within the overmold, where the recharge coil substantially encircles the first and second modules. As discussed in the Appeal Brief with respect to the obviousness rejection of claims 5 and 26, which recite features similar to those recited in claim 45, there is no rational reason why one having ordinary skill in the art would have modified Berrang such that the coil 4 (which the Examiner characterized as a recharge coil) would be located within the bridge 6 (which the Examiner characterized as an overmold<sup>2</sup>) or substantially encircle the housing sections 2 and 3 (which the Examiner characterized as first and second modules<sup>3</sup>).<sup>4</sup> Moreover, the Examiner failed to establish a *prima facie* case of obviousness with respect to claims 5, 26, and 45, e.g., by failing to identify any reason, much less a rational reason one

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<sup>1</sup> Examiner's Answer dated July 20, 2009 at pages 2 and 3.

<sup>2</sup> Final Office Action dated June 20, 2008 at page 6, item 1, and Examiner's Answer dated July 20, 2009 at page 4.

<sup>3</sup> Final Office Action dated June 20, 2008 at page 6, item 1.

<sup>4</sup> See Appeal Brief filed April 17, 2009 at pages 20 and 21.

having ordinary skill in the art would have modified Berrang in the manner proposed by the Examiner.

Berrang discloses a coil 4 that may be used to recharge a battery 18 housed within a housing section 2 of its device.<sup>5</sup> As shown in FIG. 1 of Berrang, the coil 4 does not substantially encircle the housing sections 2, 3, which the Examiner characterized as modules. The Examiner stated that claim 45 would have been obvious because “it has been held that rearranging parts of an invention involves only routine skill in the art.”<sup>6</sup> However, modification of the Berrang device to position the coil 4 around the housing sections 2, 3 requires more than just a rearrangement of parts. For example, as shown in FIG. 1 of Berrang, the coil 4 has a smaller diameter than the perimeter substantially encircling the housing sections 2, 3. Thus, the modification proposed by the Examiner would require changing the shape and size of the coil 4. Berrang does not provide any suggestion that such a modification to the coil 4 would be useful or that, so modified, the coil 4 would still be useful for its intended purpose. For example, modifying the size and shape of the coil 4 may change the principal of operation of the recharge coil.

Moreover, Berrang discloses that an “inventive feature” of its device is the location of the coil 4 away from interfering metal materials, which, according to Berrang, improves the inductive power coupling efficiency across a skin surface with an external coil.<sup>7</sup> Berrang provides absolutely no basis for concluding that positioning the coil 4 such that it substantially encircles the housing sections 2, 3 would maintain this feature of the Berrang disclosure. Accordingly, modifying the Berrang device such that the coil 4 is sized to substantially encircle the housing sections 2, 3, as suggested by the Examiner, would not have been obvious in view of the Berrang disclosure. Indeed, one having ordinary skill in the art would have consciously avoided such a modification to Berrang in view of the explicit inventive feature of the device to locate the coil 4 away from interfering metal materials.

Absent access to Appellant’s disclosure, there is no apparent reason why one having ordinary skill in the art would have modified Berrang in the manner proposed by the Examiner.

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<sup>5</sup> Berrang at column 12, lines 50–54.

<sup>6</sup> Examiner’s Answer at page 3, *citing In re Japikse*, 181 F.2d 1086, 86 USPQ 70 (CCPA 1950).

<sup>7</sup> Berrang at column 10, lines 35–39.

The Examiner failed to identify a motivation or a rational reason why a person skilled in the art would have modified the Berrang device to substantially encircle the housing sections 2, 3 with the coil 4. The only reason provided by the Examiner for modifying Berrang was that “rearranging parts of an invention involves only routine skill in the art.” However, it is established that “[t]he mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims . . . is not by itself sufficient to support a finding of obviousness.”<sup>8</sup> The prior art must provide a motivation or a reason for the modification. Thus, the Examiner has failed to establish a *prima facie* case of obviousness with respect to claim 45.

For at least these reasons, the Examiner failed to establish a *prima facie* case of obviousness with respect to claim 45, and the rejection of claim 45 as being obvious over Berrang should be reversed.

## **FIRST GROUND OF REJECTION UNDER APPEAL**

Claims 1–4, 6–9, 11–25, 27–30, 33–49, 51–54, 56, and 58–61 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Berrang.

### **CLAIM 7, 28, AND 47**

Claims 7, 28, and 47 each specify that the third module of claims 6, 27, and 46, respectively, that includes a recharge coil, is at least partially encapsulated by the overmold that also at least partially encapsulates the first and second modules of the implantable medical device. In the Examiner’s Answer, the Examiner asserted that the figures of Berrang, and, particularly FIG. 17, illustrate a coil 4 that is partially encapsulated by an overmold.<sup>9</sup> The Examiner’s characterization of Berrang is erroneous and is unsupported by the Berrang disclosure.

The Examiner characterized the bridge 6 of the Berrang device as an overmold.<sup>10</sup> Berrang does not disclose or even suggest that the bridge 6 at least partially encapsulates the coil 4, as asserted by the Examiner. Neither FIG. 17 nor the description of FIG. 17 refers to the

<sup>8</sup> MPEP 2144.04(VI)(C), *citing Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (BPAI 1984).

<sup>9</sup> Examiner’s Answer dated July 20, 2009 at page 8.

<sup>10</sup> Final Office Action date June 20, 2008 at page 6, item 1.

location of the bridge 6 in FIG. 17 or suggests that the bridge 6 at least partially encapsulates the coil 4. Berrang provides very little description of FIG. 17. To the extent Berrang describes FIG. 17, Berrang merely states that FIG. 17 illustrates a coil between two housing sections.<sup>11</sup> Therefore, the Berrang reference fails to provide any support for the Examiner's assertion that FIG. 17 or any other figure of Berrang illustrates the bridge 6 at least partially encapsulating the coil 4.

As shown in FIG. 1 of Berrang, the bridge 6 appears to be adjacent to the coil 4, rather than at least partially encapsulating the coil 4. Moreover, the arrangement of the bridge 6 relative to the coil 4 does not permit the bridge 6 to even contact the coil 4. Berrang states that the bridge 6 and housing sections 2, 3 are coated in gold. Thus, the bridge 6 cannot at least partially encapsulate the housing sections 2, 3, the bridge and housing sections then being coated in gold, and also at least partially encapsulate the coil 4, which is located outside of the gold coating.

For at least these reasons, the Examiner failed to establish that Berrang discloses each and every element of claims 7, 28, and 47, and the rejection of claims 7, 28, and 47 should be reversed.

#### **CLAIMS 9, 30, AND 49**

Claims 9, 30, and 49 each specify that the third module of claims 6, 27, and 46, respectively, is located outside of the overmold and a flexible tether member connects the third module to the overmold. As discussed in the Appeal Brief, Berrang not only fails to disclose that the coil 4 comprises a housing, but Berrang also fails to disclose an arrangement in which the coil 4 is located outside of an overmold and connected to the overmold via a flexible tether member.

In the Examiner's Answer, the Examiner clarified the rejection of claims 9, 30, and 49. The Examiner stated that "onle [sic] one of the embodiments, the triangular configurations, as depicted in figures 15 and 16 [of Berrang], the third module, coil 4, is connected to the overmold

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<sup>11</sup> Berrang at column 9, lines 26–28.

by a flexible tether and thus located outside of the flexible overmold.<sup>12</sup> The Examiner has mischaracterized the Berrang reference, and, therefore, the rejection of claims 9, 30, and 49 that relies on the mischaracterization of Berrang was erroneous.

In the final Office Action, the Examiner stated that in the example of the device shown in FIG. 1, the coil 4 is located in the bridge 6 (which the Examiner characterized as an overmold), and in the example shown in FIGS. 15 and 16 of Berrang, the coil 4 is located outside of the bridge 6 and connected to the bridge 6 via a flexible tether member.<sup>13</sup> The Examiner, therefore, asserted that Berrang discloses two different arrangements of the coil 4 relative to the bridge 6. However, Berrang offers absolutely no support for the Examiner's assertion that FIGS. 1, 15, and 16 illustrate different positions of the coil 4 with respect to the bridge 6.

With respect to FIGS. 15 and 16, Berrang merely states that FIGS. 15 and 16 "illustrate alternate embodiments . . . showing the coil 4 and the two housing sections."<sup>14</sup> Berrang states that FIG. 15 illustrates a configuration of a coil and two housing sections, where the coil is inferior, and FIG. 16 illustrates a configuration in which the coil is anterior.<sup>15</sup> The inferior and anterior locations of the coil 4 have nothing to do with the position of the coil relative to the bridge 6. In addition, Berrang does not state that the coil 4 is connected to the bridge 6 in a different manner in FIGS. 15 and 16 as compared to the examples shown in the other figures, such as FIG. 1. Thus, contrary to the Examiner's assertions, Berrang does not disclose both an implantable medical device in which a recharge coil is within an overmold and an implantable medical device in which a recharge coil is located outside an overmold and is connected to the overmold via a flexible tether member.

The Examiner has failed to demonstrate that Berrang discloses that the coil 4 is both at least partially encapsulated by an overmold and located outside of an overmold. For at least these reasons, the rejection of claims 9, 30, and 49 should be reversed because the Examiner has failed to establish a *prima facie* case of anticipation with respect to claims 9, 30, and 49.

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<sup>12</sup> Examiner's Answer dated July 20 2009 at page 8.

<sup>13</sup> Final Office Action dated June 20, 2008 at pages 6 and 7, item 1.

<sup>14</sup> Berrang at column 15, line 66 – column 16, line 2.

<sup>15</sup> Berrang at column 9, lines 20–25.

### **CLAIM 11**

Claim 11 specifies that the overmold of claim 1 completely encapsulates the first and second modules. Berrang fails to disclose or suggest an overmold that completely encapsulates the first and second modules. The Examiner characterized the bridge 6 of the Berrang device as an overmold and stated that the bridge 6 “partially encapsulates the . . . first and second housing [sic].”<sup>16</sup> Claim 11, on the other hand, requires an overmold that completely encapsulates first and second modules.

The Examiner provided clarification of the rejection of claim 11 in the Examiner’s Answer. In particular, the Examiner stated that the Examiner considers the bridge 6 disclosed by Berrang to completely and at least partially encapsulate the first and second housing sections (the first and second modules according to the Examiner).<sup>17</sup> Berrang offers no support for the Examiner’s position that the bridge 6 completely encapsulates the first and second housing sections. As shown in FIGS. 1 and 2 of Berrang, the bridge 6 is merely adjacent the housing sections 2, 3 and neither encapsulates nor completely encapsulates the housing sections 2, 3. The bridge 6 is only adjacent to one side of the housing sections 2, 3. Thus, it is clear that Berrang does not disclose or even suggest that the bridge 6 completely encapsulates the housings sections 2, 3.

For at least these reasons, the Examiner failed to establish that Berrang discloses each and every element of claim 11, and the rejection of claim 11 should be reversed.

### **CLAIM 56**

Independent claim 56 is directed to an implantable medical device that comprises a first module comprising control electronics within a first housing, a second module comprising a recharge coil within a second housing, a third module comprising a rechargeable power source within a third housing, an overmold that at least partially encapsulates the first and third housings, and a flexible tether member that connects the overmold and the second housing. Berrang does not teach or suggest such elements, much less an arrangement in which control

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<sup>16</sup> Final Office Action dated June 20, 2008 at page 6, item 1 (emphasis added).

<sup>17</sup> Examiner’s Answer dated July 20, 2009 at page 8.

electronics and a rechargeable power source are provided in separate housings that are at least partially encapsulated by an overmold, and a recharge coil is provided within another housing that is connected to the overmold. Furthermore, the Examiner failed to meet the burden of demonstrating that Berrang anticipates such an arrangement of the control electronics, rechargeable power source, and recharge coil.

The Examiner stated that FIGS. 15–18 of Berrang, and particularly FIG. 17, illustrate a coil 4 that is partially encapsulated by a bridge 6 (which the Examiner characterized as an overmold).<sup>18</sup> As discussed above with respect to claims 7, 28, and 47, neither FIG. 17 nor the description of FIG. 17 suggests that the bridge 6 is shown in FIG. 17 or that the bridge 6 at least partially encapsulates the coil 4. Moreover, FIGS. 15, 16, and 18 also fail to illustrate a bridge 6 that partially encapsulates a coil 4.

FIGS. 15–18 do not even identify the bridge 6, and the description of FIGS. 15–18 does not provide any details as to the arrangement between the bridge 6 and the coil. The little description Berrang provides of FIGS. 15–18 states that FIGS. 15–18 illustrate alternate embodiments for the configuration of the coil and housing sections 2, 3, where the coil is inferior (FIG. 15), anterior (FIG. 16), between the housing sections (FIG. 17), and posterior (FIG. 18).<sup>19</sup> Thus, FIGS. 15–18 merely illustrate different locations of the coil when implanted within a patient, and do not disclose or suggest a coil partially encapsulated by an overmold.

The Examiner appears to have misinterpreted the language of claim 56. The Examiner asserted that Berrang anticipates independent claim 56 because FIGS. 15–18 of Berrang “depict the two modules and the third module, containing the coil . . . the coil is partially encapsulated by the overmold”<sup>20</sup> However, claim 56 does not require an overmold that at least partially encapsulates a housing containing a coil. Instead, claim 56 specifies that an overmold at least partially encapsulates a first housing of a first module comprising control electronics and a third housing of a third module comprising a rechargeable power source. Claim 56 specifies that the module comprising a recharge coil is connected to the overmold via a flexible tether member.

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<sup>18</sup> Examiner’s Answer dated July 20, 2009 at page 10.

<sup>19</sup> Berrang at column 9, lines 20–32.

<sup>20</sup> Examiner’s Answer dated July 20, 2009 at pages 9 and 10.

Thus, the Examiner's rejection of claim 56 should be reversed on at least the basis that the Examiner misinterpreted claim 56.

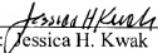
### CONCLUSION

For at least these reasons and the reasons discussed in Appellant's Appeal Brief, the Examiner has failed to meet the burden of establishing a *prima facie* case of nonpatentability with respect to Appellant's claims 1-31 and 33-61. In view of Appellant's arguments present in this Reply Brief and in the previously-filed Appeal Brief, the final rejection of Appellant's claims was improper and should be reversed. Reversal of all pending rejections and allowance of all pending claims is respectfully requested.

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